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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,290	05/08/2001	Norbert F Schnell	P 279455	2741

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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,290	SCHNELL ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 6* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 8 May 2001 as the U.S. National stage of International Patent Application PCT/GB99/03789 filed 12 November 1999, which claims benefit of the British Patent Application GB 9825055.8 filed 17 November 1998. The Preliminary Amendments filed 8 May 2001 (Paper No. 5) and 14 August 2002 (Paper No. 8) have been entered. Claims 1-7 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that, because claim 7 depends from claim 1, claim 1 links elected and non-elected inventions and therefore must be examined pursuant to MPEP 809.04. This is not found persuasive because, although claim 7 depends from claim 1 in that the product to which claim 7 is directed can be identified by the method of claim 1, the subject matter of claim 7 is not encompassed by the subject matter of claim 1 because the claims are directed to different statutory classes of invention (i.e., claim 1 is directed to a method while claim 7 is directed to a product). Furthermore, claim 7 is a product by process claim; thus, the limitations of claim 1 are not afforded patentable weight in the examination of claim 7. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a

product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Applicant states that the generic claims must be examined throughout their full scope. Applicant's point is taken, and claim 1 will be examined over its full scope as a method. Because claim 1 is not directed to a product, the subject matter of claim 7 will not be examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

Claim 6 is objected to because of the following informalities: While there is no set statutory form for claims, the present Office practice is to insist that each claim must be expressed as a complete sentence (see MPEP 608.01). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to an engineered cell whose ability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids, and a method of using said engineered cell to assay for an IPC synthase inhibitor. Given their broadest reasonable interpretation, the engineered cell of the claims encompasses a genus of any and all cells of all kingdoms, genera and species engineered by any and all means to have the phenotypic limitations of the claims. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics (see MPEP 2163 (ii)). In the instant case, the specification provides two strains of *S. cerevisiae* (i.e., lcb1/SLC-1 and lcb1/pGPD-SLC-1) having the functional limitations of the engineered cell, both of which have been reduced to practice either in the prior art or application. The disclosed species represent a single species of organism comprising identical genetic mutations, differing only in the level of expression of the SLC1-1 gene. Clearly, the disclosed species are not

representative of the full scope of the genus, which encompasses all organisms comprising any and all genetic mutations giving rise to the phenotype set forth in the claims. In the third full paragraph on page 2, the specification also teaches, "[a]ny convenient host cell strain may be used provided that it can function as a host for a fungal IPC synthase gene". Thus, the disclosure sets forth the ability to host a fungal IPC synthase gene as the relevant identifying characteristic of the host cell of the claims. However, this cannot be the case because wild-type fungi expressing IPC synthase do not have the lsb1/SLC-1 phenotype.

Description of engineered cells whose capability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids beyond the explicitly disclosed *S. cerevisiae* (lcb1/SLC-1) or *S. cerevisiae* (lcb1/pGPD-SLC-1) amounts to no more than a recitation of function. However, it is not sufficient to define an organism solely by its principal biological property, (i.e., exogenous phytosphingosine dependent sphingolipid synthesis and ability to grow via compensatory phospholipids) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any engineered cell with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all engineered cells that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods

first requires an adequate description of the materials (i.e., specific engineered cells), which provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of engineered cells encompassed by the claims. Therefore, only the described *S. cerevisiae* (lcb1/SLC-1) or *S. cerevisiae* (lcb1/pGPD-SLC-1) meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an engineered *S. cerevisiae* comprising the lcb1/SLC1-1 genotype and further overexpressing SLC-1, and a method identifying a selective IPC synthase inhibitor using said engineered *S. cerevisiae*, does not reasonably provide enablement for any and all cells having the phenotype of exogenous phytosphingosine dependent sphingolipid synthesis and ability to grow via compensatory phospholipids or methods of identifying IPC synthase inhibitors using any and all cells having that phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement

and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and breadth of the claims: The instant invention is directed to a method of screening for potential antifungal agents, comprising contacting a test compound with engineered cells whose capability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids, and engineered cells to be used in the method of screening. The claims thus encompass a method of screening for potential antifungal agents using any cell having the phenotypic characteristics set forth in the claims.

State and level of predictability in the art: The art, exemplified by Nagiec *et al.* (1997) *J. Biol. Chem.* 272:9809-9817, teaches a single example of an organism having the phenotype of the organism to be used in the claimed method (i.e., *S. cerevisiae* (lcb1/SLC1-1)) and that the organism can be used to screen for IPC synthase inhibitors.

Amount of direction provided by the inventor and existence of working examples: The instant disclosure teaches that *S. cerevisiae* (lcb1/SLC1-1) "grows very poorly and is extremely sensitive to any environmental influences such as for example freezing. This strain is simply not robust enough for screening purposes" (paragraph bridging pages 1 and 2). Thus, the specification teaches that the only known engineered cell having the lcb1/SLC1-1 phenotype,

outside of S. *cerevisiae* (lcb1/pGPD-SLC-1) disclosed in the instant application, would not work for the purpose set forth in the specification and, therefore, that the functional limitations set forth in the claims do not predictably identify a useful organism. Although the specification teaches that *S. cerevisiae* (lcb1/SLC1-1) can be further modified to provide a useful organism by overexpressing SLC-1, there are no teachings therein that would enable the skilled artisan to make other useful organisms having the phenotype set forth in the claims without resorting to blind trial and error experimentation.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the level of skill in the art is high, for the reasons set forth above, the teachings in the specification and prior art would not enable the skilled artisan to make an engineered cell wherein the capability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids that could be used according to the disclosed method, other than a cell further overexpressing SLC-1, without resorting to undue experimentation to identify other strains that could be used in the method. Further, the teachings of the specification and prior art clearly do not teach the skilled artisan how to practice the claimed method using all cells having the phenotype set forth in the claims because the specification teaches that *S. cerevisiae* lcb1/SLC1-1 would not work in the claimed method. Therefore, practicing the invention commensurate with the full scope of the claims would require undue experimentation.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the specifically named *S. cerevisiae* strain (lcb1/pGPD-SLC-1) or further engineered strains of *S. cerevisiae* (lcb1/pGPD-SLC-1). Because the complexity of a cell precludes independent derivation of *S. cerevisiae* (lcb1/pGPD-SLC-1) with substantially identical characteristics, one would have to have access to the named strain in order to use the claimed invention. Although the strain is described in the specification, no evidence is provided that would indicate that it is readily available to the public. Without such availability practicing the invention is impossible and the claims are therefore not enabled. This rejection can be traversed by perfecting a deposit of the *S. cerevisiae* (lcb1/pGPD-SLC-1) strain according to the rules for deposit of biological material (M.P.E.P. 2401-2411).

Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
March 28, 2003

JAMES KETTER
PRIMARY EXAMINER